

## **REMARKS/ARGUMENTS**

Responsive to the Office Action dated December 5, 2008, Claims 1-3, 6-13 and 16 have been cancelled and new Claims 17-36 have been added. Claims 4-5 and 14-15 were previously withdrawn as being drawn to a non-elected invention or species. Accordingly, Claims 17-36 are currently pending for prosecution with Claims 17 and 27 being independent.

### **I. SPECIFICATION OBJECTION**

The specification was objected to because it contained an embedded hyperlink. Applicant has therefore amended the specification to delete the embedded hyperlink at issue and respectfully requests withdrawal of this objection.

### **II. CLAIM OBJECTIONS**

Claims 2-3 and 6-13 were objected to under 37 C.F.R. 17.75(c) as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant has canceled these claims thereby rendering this objection moot.

### **III. CLAIM REJECTIONS UNDER 35 U.S.C. § 112**

Claims 2-3 and 6-13 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant has canceled these claims thereby rendering this rejection moot.

### **IV. CLAIM REJECTIONS UNDER 35 U.S.C. § 102**

Claims 1-3, 8 and 13 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,402,941 to Vaillancourt et al. ("Vaillancourt"). Although the claims at issue have

been canceled, Applicant has added new claims 17-36 and will address this rejection as it applies to the new claims. Accordingly and for the following reasons, Applicant respectfully requests reconsideration and withdrawal of this rejection.

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). Vaillancourt discloses a veterinary composition for preventing feline urological syndrome in cats wherein the composition is applied to cat litter such that, when a cat uses the litter box, the composition impregnates the cat's paws so that the cat unconsciously ingests the medicine when it cleans itself by licking its paws and fur.

Applicant respectfully submits that the present invention is not anticipated by Vaillancourt because Vaillancourt fails to teach each and every element of the claims. First, the present invention is directed to a method for treating livestock rather than cats. Second, Applicant's claimed invention involves applying a veterinary composition directly to the muzzle of the animal whereas Vaillancourt's method uses an indirect application method. Finally, the claimed veterinary composition includes a post-application identifier to signify that the animal has been treated. Vaillancourt does not provide any post-application identification method at all.

Accordingly, because Vaillancourt fails to teach each and every element of the claims at issue, Vaillancourt does not anticipate the present invention.

## **V. CLAIM REJECTIONS UNDER 35 U.S.C. § 103**

### **A. Obviousness**

When determining the question of obviousness, underlying factual questions are presented which include (1) the scope and content of the prior art; (2) the level of ordinary skill in the art at the time of the invention; (3) objective evidence of nonobviousness; and (4) the differences between the prior art and the claimed subject matter. Graham v. John Deere Co., 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966). Moreover, with regard to the last prong of the Graham inquiry, “[t]o determine whether there was an apparent reason to combine the known elements in the way a patent claims, it will often be necessary to look to interrelated teachings of multiple patents; to the effects of demands known to the design community or present in the marketplace; and to the background knowledge possessed by a person having ordinary skill in the art. To facilitate review, this analysis should be made explicit.” KSR International v. Teleflex Inc., 127 U.S. 1727 (2007).

Applicant does not contest that the references that have been cited and relied on by the Examiner have at least marginal pertinence to the particular problem(s) solved by the present invention in that the references disclose methods for treating or vaccinating animals. Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1535, 218 USPQ 8781, 8786 (Fed. Cir. 1983).

The person of ordinary skill in the art is a hypothetical person who is presumed to know the relevant prior art. Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc., 807 F.2d 955, 962, 1 USPQ2d 1196, 1201 (Fed. Cir. 1986). The level of ordinary skill in the art of veterinary compositions and methods for treating animals may be determined by looking to the references of record. In re GPAC, Inc., 57 F.3d 1573, 35 USPQ2d 1116 (Fed. Cir. 1995). The references of record in this case reveal that a moderate level of sophistication in the veterinary arts is associated with one of ordinary skill. Thus, Applicant submits that, as substantiated by the cited references, those with at least a bachelor's degree in chemistry or biochemistry or substantial

experience in the veterinary industry or the like would most likely be a person with ordinary skill in this field of endeavor.

With respect to objective evidence of nonobviousness, Applicant submits that the record supports the conclusion that there are long-felt but unsolved needs met by the present invention. The present invention is directed to the particular problem of providing a method for treating livestock with a veterinary composition that avoids the use of needles, administers the composition to the animal's mucosal membranes, avoids close physical contact with the animal, and provides a visual indicator of vaccination. The present application is directed to a method of treating livestock that includes applying an effective dose of a veterinary composition directly to the muzzle of animal whereas the animal distributes the medicine into its mucosal membranes with its tongue and the method also includes a post-application identifier. These features represent a solution to long felt needs in the art that could not be met by the known prior art.

Finally, *prima facie* obviousness requires that there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references. This motivation-suggestion-teaching test informs the Graham analysis. “To reach a non-hindsight driven conclusion as to whether a person having ordinary skill in the art at the time of the invention would have viewed the subject matter as a whole to have been obvious in view of multiple references,” there must be “some rationale, articulation, or reasoned basis to explain why the conclusion of obviousness is correct.” In re Kahn, (Fed. Cir. 2006). The *KSR International* decision by the Supreme Court has not eliminated the motivation-suggestion-teaching test to determine whether prior art references have been properly combined. Rather, in addition to the motivation-suggestion-teaching test, the Court discussed that combinations of known technology that are “expected”

may not be patentable. Stated in the affirmative, therefore, combinations are nonobvious and patentable if unexpected. In the present application, no single prior art reference nor any combination thereof meets the claimed limitations of Applicant's invention.

**B. Rejection of Claims 1-3, 6-9, 11 and 16 over Merck in view of Vaillancourt**

Claims 1-3, 6-9, 11 and 16 were rejected under 35 U.S.C. 103(a) as being unpatentable over Merck Veterinary Manual 8<sup>th</sup> Edition 1998 (whole book) in view of Vaillancourt. For the following reasons, Applicant respectfully requests reconsideration and withdrawal of this rejection.

The Office Action asserts that "[t]he Merck Veterinary Manual teaches many pharmaceuticals and vaccines for prevention and/or treatment of various diseases . . . . The manual teaches that drugs can be administered orally via paste or liquid (p. 1650) or vaccines taken in orally via feed or drinking water." Furthermore, the Office Action asserts that "Vaillancourt et al teaches a method for treating a feline or other animals to achieve a positive effect on the health of the animal comprising applying a biologically-active compound to the muzzle (impregnating muzzle with medicine) wherein the animal subsequently cleans itself and then ingests the medicine when it cleans itself by licking (with tongue). Said method of licking the muzzle necessarily means distributing the medicine into nasal or oral mucosa." Moreover, it is asserted that "Vaillancourt teaches that said method of administration i.e. applying to the muzzle can be used for administering any other preparation or compositions for preventing or treating other diseases."

Therefore, the Office Action concludes, it "would have been *prima facie* obvious to apply any of the biologically active compounds of The Merck Veterinary to the muzzle of a [sic] animal as Vaillancourt teaches that an animal in the process of cleaning itself licks the compound

and ingests the compound into the oral mucosa. Said method of licking the muzzle will also distribute the compound into the nasal cavity and nasal mucosa. The motivation is provided by Vaillancourt who teaches that said method of administration i.e. applying to the muzzle can be used for administering any other preparation or compositions for preventing or treating other diseases (column 4 lines 25-33) thus avoiding any difficulty in orally administering medicine to an animal (Vaillancourt column 2 lines 17-28). Furthermore, it is *prima facie* obvious that one of skill in the art would reasonable [sic] spread the liquids or pastes comprising the biologically active compound unto the muzzle of said animal when applying to the muzzle."

Applicant respectfully traverses the assertion that the Merck and Vaillancourt references, when combined, teach or suggest all of Applicant's claim limitations. While Applicant does not dispute that the use of vaccines, pharmaceuticals, live, attenuate or killed biological organisms in the treatment or prevention of disease in all types of animals is well known in the art, Applicant's claimed invention directed to a method of administration of these compositions is not rendered obvious by the combination of Merck and Vaillancourt for the reasons discussed hereinbelow.

#### **1. Vaillancourt teaches away from Applicant's claimed invention.**

First, Applicant respectfully submits that Vaillancourt teaches away from directly applying a veterinary composition to the muzzle of the animal. In fact, Vaillancourt's method teaches applying the composition to a substrate (litter) in order for the animal to passively pick up particulates of medication on its feet, fur and muzzle. The animal only ingests the medication by licking (cleaning) its feet and fur. The main advantage of Vaillancourt's litter "whose particles are covered with an external layer of medicine, lies in that the animal impregnates its paws, part of its fur and its muzzle with medicine without noticing it . . ." (col.2, ll. 41-44). Vaillancourt's passive method of administering a veterinary composition is asserted to provide

the following advantages: the convalescent animal does not undergo any stress, and the danger of the owner of the cat being bitten or scratched is reduced. Vaillancourt therefore teaches using a passive, non-direct method of administering a composition to a domestic animal mainly to reduce any negative impact on the animal and the pet's owner.

Vaillancourt's method cannot be utilized when administering veterinary compositions to livestock. Vaillancourt clearly limits his invention to using litter as the carrier for the veterinary composition that is applied passively to animal's paws, fur and muzzle. Vaillancourt defines litter as "every 'substance' placed in a container or tray and used as a toilet place for a domestic cat or any other animal kept in captivity." (Col.2, ll. 36-39). While Vaillancourt's method is not limited specifically to cats nor is it limited to the veterinary composition recited (Col. 4, lines 23-28), Vaillancourt's method is specifically limited to only using the disclosed litter as the method of administering a veterinary composition.

Vaillancourt does not teach, suggest or motivate using any other method to administer the veterinary composition other than prior art (orally and through food) or using the litter as a vehicle for passive, not direct, application. Vaillancourt's method is limited to only animals, like cats, that use litter as part of their behavioral life. Clearly, livestock do not use litter as part of their behavioral life; therefore, Vaillancourt's method cannot successfully or effectively be used to administer veterinary compositions to livestock.

Moreover, Vaillancourt actually teaches away from applying the veterinary composition directly to the muzzle of an animal. Vaillancourt continually promotes that the advantage of using Vaillancourt's method is that a pet owner does not have directly administer medication to felines or other animals that use litter as part of their behavioral life. Vaillancourt's further touts the fact that using Vaillancourt's passive, indirect administrative method, the animal does not

undergo stress and the danger of the owner getting scratched or bitten is reduced. Following Vaillencourt's teaching, there is even more motivation to develop an indirect application method when dealing with livestock rather than the direct application method of the present invention.

Cattle weigh upwards of one thousand pounds and can trample or kick a handler that gets too close when they feel threatened. Cattle do not like people to touch their muzzles. Upon becoming aggravated or threatened, a cow, steer or bull may trample or kick a handler, potentially causing serious or life threatening injury. Clearly, Vaillancourt provides much more motivation to develop an indirect, passive application method as taught in Vaillancourt when applying medicine to cattle. Particularly if the potential effects on the handler are significantly more severe than a cat scratch or small animal bite. However, Applicant's proposed invention requires personal proximity in order to apply the composition directly to the muzzle. Thus, Applicant's proposed application method goes against any teaching, suggestion or motivation provided by Vaillancourt.

**2. Vaillancourt does not disclose using a post-application identifier to identify animals already treated.**

Vaillancourt does not support a rejection based on obviousness because Vaillancourt does not teach, suggest or motivate the use of a post-application identifier. Vaillancourt's method is functionally limited to use for a small number of domesticated animals that use litter in their behavioral life. Only a few animals at a time can use each litter box. Vaillancourt does not teach, suggest, or motivate how Vaillancourt's method could be used to apply veterinary compositions to larger animals that do not use litter or a much larger number of animals such as a cattle herd. In livestock production, litter is not part of the cattle growing confines, nor does livestock behavior justify it as a realistic alternative. Further, there are often circumstances when

multiple animals, even whole herds, require administration of a pharmaceutical or vaccine in livestock production. Sometimes, the failure to treat one animal could endanger an entire herd. Therefore, Applicant's invention incorporates a "post-application identifier" that allows for thorough administration of the composition to a large number of animals, helps to ensure only the animals intended receive the dose of composition and that an animal does not receive more than one dose that could harm the animal. This feature is especially applicable when dealing with larger numbers of animals such as a livestock herd. Vaillancourt does not teach, suggest or motivate the use of a "post-application identifier" as a feature in the veterinary composition or the method Vaillancourt discloses.

**3. Vaillancourt relies on the animal's feet as the primary carrier of medicine for ingestion by the animal.**

Vaillancourt discloses the animal's feet as the part of the body most responsible for the passive administration of medicine using Vaillancourt's litter administration method.

Vaillancourt particularly emphasizes the area of a cat's paw in comparison to the area of the litter bed when estimating how much medicine is picked up by a cat at each visit to the litter. (Col. 2, ll. 51-56). Vaillancourt discloses that the medicine is ingested when the cat licks its paws and fur. (Col. 2, ll. 44-45). Among domestic animals, the cat has the greatest capability to pronate specifically the front paws. In other words, a cat is relatively unique in its ability to use its front paws to clean its face in a manner similar to human using a wash cloth. Cattle do not have this capability to pronate their feet and, moreover, Vaillancourt's method cannot be applied to livestock as livestock do not habitually clean themselves by licking their hooves.

Livestock could not ingest enough medicine to be an effective dose using Vaillancourt's method. Unlike cats, that are "known to be very clean animals which lick themselves after

urinating or passing stools," (col. 2, ll.46-48), livestock do not have the behavioral instinct to thoroughly clean their feet with their tongue. Any visit to a farm or ranch makes this point evident as these animals roll in mud and dirt to cool off and reduce annoyance by insects. Livestock do not use litter nor do livestock clean their feet with their tongue. Thus, Vaillancourt's method is an inapplicable method of administering veterinary compositions to livestock because Vaillancourt's method is based on the animal's paws being the primary carrier in which the effective amount of medicine transfers from the medicine-containing litter to the animal ingesting the medicine by licking its paws and fur.

Further, while Vaillancourt specifically identifies the cat's paws, fur and muzzle as being impregnated with the medicine (col. 2, ll. 42-43), Vaillancourt only discloses that the medicine is ingested when the cat licks its paws and fur. (Col. 2, ll. 44-45). Vaillancourt does not disclose that the cat ingests the medicine by licking the muzzle with particularity. Thus, Vaillancourt only discloses medicine being impregnated on the muzzle, but does not disclose that the medicine is ingested by the animal by licking the muzzle.

**4. Vaillancourt does not disclose a method that can effectively deliver a single effective dose to an animal though its muzzle, but relies on continuous chance dosages carried by the animal's feet to provide helpful amounts of composition.**

Vaillancourt's method can only be used to apply a continuous, unpredictable dose of medication to an animal and does not allow providing a single, effective dose of medication to an animal. Vaillancourt estimates that a cat using the litter will pick up 5-15% of medicine added to its litter each day. (Col 2, ll. 54-56). This is a very unpredictable range of dosage. In 7 days, an animal could pick up 35-100% of the medicine added to the litter. Vaillancourt's method is

applicable when a specific dosage is not required and only when the animal's behavioral pattern allows for the use of the litter.

Livestock do not follow a behavioral pattern of using litter. Further, the location, area and methods required in raising livestock to not facilitate Vaillancourt's continual dosage method. Livestock graze in large pastures or feedlots. Livestock do not excrete wastes in a single, predictable location, nor do they clean their feet with their tongue. Therefore, Vaillancourt's method is ineffective in administering veterinary compositions to livestock.

Livestock growers require veterinary compositions to be administered to an animal in a single, effective dose for the majority of applications. Vaillancourt's method as taught or suggested cannot meet this requirement. Vaillancourt relies on the behavioral instincts of an animal to go to one predictable location to excrete wastes at least once a day and then clean themselves by licking their feet and fur soon after going to that place. The animal must clean themselves soon after stepping on the litter so that the medicine does not rub off when the animal walks around its confined location. Further, Vaillancourt's method only allows for 5-15% of the effective amount of medicine to be ingested by an animal each day. Livestock growers require that an animal be treated with one effective dose in a single application. Vaillancourt does not facilitate one effective dose in a single application and Vaillancourt's method cannot predict the dosage amount per day or total dosage amount ingested by the animal, other than a range which over a 7 day period can vary by 65%.

Accordingly, The Merck Veterinary Manual and Vaillancourt, individually and in combination, fail to teach or suggest the combination asserted by the Examiner. Further, neither of the references teaches nor suggests all of the elements of independent Claims 17 and 27 and no resultant method could have been created from these references that would meet the

limitations of these claims. Vaillancourt teaches away from direct application of a veterinary composition to the animal's muzzle and also fails to teach or suggest the use of a "post-application identifier." Moreover, Vaillancourt's method relies primarily on the animal's feet to be the carrier of medicine from the litter to being ingested by the animal and does not allow for a single, predictable, effective dose of the veterinary composition. Therefore, one of ordinary skill in the art would not have arrived at Applicant's claimed invention because Applicant's invention would not be an "expected" result of the combination of these references since both references, individually and in combination, fail to meet all the limitations of the subject claims. Accordingly, Applicant's independent Claims 17 and 27 and the claims depending therefrom are nonobvious.

**C. Rejection of Claims 1-3, 6-7, 9, 12, 13, and 16 over Chu in view of Vaillancourt**

In addition, Claims 1-3, 6-7, 9, 12, 13, and 16 were rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Publication No. 2002/0025325 A1 to Chu et al. in view of Vaillancourt. For the following reasons, Applicant respectfully requests reconsideration and withdrawal of this rejection.

The Office Action asserts that "Chu et al teaches a biologically active composition comprising live, attenuated or killed biological organisms e.g. bacteria such as *Chlamydia psittaci* which causes Chlamydiosis disease of the eye, or *Mycoplasma hyponeumoniae* (respiratory disease) or rickettsia (*Ehrlichiosis canis* which causes hemolymphatic disease) and a palatable flavorant such as plant flavorings (strawberry) or sugars e.g. glucose or fructose syrups - syrups also provide enhanced viscosity." In combination with Vaillancourt, therefore, the Office Action concludes that it "would have been *prima facie* obvious to apply any of the

biologically active compounds of Chu et al to the muzzle of an animal as Vaillancourt teaches that an animal in the process of cleaning itself licks the compound and ingests the compound into the oral mucosa . . . . Furthermore, it is *prima facie* obvious that one of skill in the art would reasonable [sic] spread the liquid comprising the biologically active compound unto the muzzle of said animal when applying to the muzzle."

As discussed above, Applicant does not dispute that the use of vaccines, pharmaceuticals, live, attenuate or killed biological organisms in the treatment or prevention of disease in all types of animals is well known in the art. However, Applicant does respectfully traverse the assertion that the Chu and Vaillancourt references, when combined, teach or suggest all of Applicant's claim limitations. Applicant's claimed invention directed to a method of administration of these compositions is not rendered obvious by the combination of Chu and Vaillancourt for the same reasons discussed above in association with the rejection over Merck and Vaillancourt. Applicant therefore respectfully submits that independent Claims 17 and 27 and the claims depending therefrom are nonobvious.

**D. Rejection of Claims 1-3, 6-7, 9, 10 and 16 over Livingston in view of Vaillancourt**

Finally, Claims 1-3, 6-7, 9, 10 and 16 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 4,692,412 to Livingston et al. in view of Vaillancourt. For the following reasons, Applicant respectfully requests reconsideration and withdrawal of this rejection.

The Office Action asserts that "Livingston et al teaches a biologically active composition comprising killed biological organisms e.g. bacteria such as *Progenitor cryptocides* which causes diseases of the integument system (connective tissue) or urinary system (kidney) for the

treatment of animals and teaches oral administration." It is admitted that "Livingston et al does not teach applying said biologically-active compound to the muzzle of an animal which subsequently cleans its muzzle with its tongue, thereby distributing the compound into the oral and/or nasal cavities of the animal to contact the nasal and/or oral mucosa." Therefore, the Office Action concludes that it "would have been prima facie obvious to apply the biologically active compound of Livingston et al to the muzzle of an animal as Vaillancourt teaches that an animal in the process of cleaning itself licks the compound and ingests the compound into the oral mucosa . . . . Furthermore, it is prima facie obvious that one of skill in the art would reasonable [sic] spread the liquid comprising the biologically active compound unto the muzzle of said animal when applying to the muzzle."

As discussed above, Applicant does not dispute that the use of vaccines, pharmaceuticals, live, attenuate or killed biological organisms in the treatment or prevention of disease in all types of animals is well known in the art. However, Applicant does respectfully traverse the assertion that the Livingston and Vaillancourt references, when combined, teach or suggest all of Applicant's claim limitations. Applicant's claimed invention directed to a method of administration of these compositions is not rendered obvious by the combination of Livingston and Vaillancourt for the same reasons discussed above in association with the rejection over Merck and Vaillancourt. Applicant therefore respectfully submits that independent Claims 17 and 27 and the claims depending therefrom are nonobvious.

#### **IV. CONCLUSION**

Applicant respectfully submits the claims and the application are in condition for allowance and such is courteously solicited. If any issue regarding the allowability of any of the pending claims in the present application could be readily resolved, or if other action could be

taken to further advance this application such as an Examiner's amendment, or if the Examiner should have any questions regarding the present amendment, it is respectfully requested that the Examiner please telephone Applicant's undersigned attorney in this regard. Should any fees be necessitated by this response, the Commissioner is hereby authorized to deduct such fees from Deposit Account No. 11-0160.

Respectfully submitted,

Date: 3-5-2009

  
\_\_\_\_\_  
Lara S. Dickey  
Reg. No. 48,161  
Husch Blackwell Sanders LLP  
4801 Main St., Suite 1000  
Kansas City, MO 64112  
816-983-8000  
ATTORNEYS FOR APPLICANT